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**FROM** : Oleg F. Kaplun, Esq.  
Fay Kaplun & Marcin, LLP

**DATE** : February 2, 2007

**SUBJECT** : Oncology  
U.S. Patent Appln. Serial No. 10/608,660  
for *Pressure Actuated Valve with Improved Biasing Member*  
Our Ref.: 10123/00201

**NUMBER OF PAGES INCLUDING COVER :** 17

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Attorney Docket No. [10123/00201]

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Weaver et al.  
Serial No. : 10/608,660  
Filed : June 27, 2003  
For : Pressure Actuated Valve with Improved Biasing Member  
Group Art Unit : 3761  
Examiner : Leslie R. Deak

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By:

Date: February 2, 2007

Oleg F. Kaplun (Reg. No. 45,559)

**TRANSMITTAL**

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on December 4, 2006 for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: February 2, 2007

By:

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Attorney Docket No. [10123/00201]

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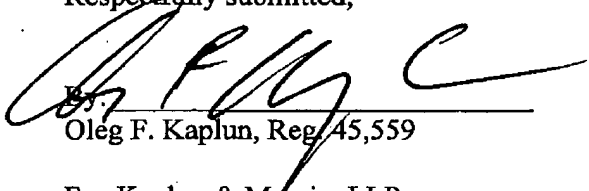
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PATENT  
Attorney Docket No.: 10123 - 00201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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In re Application of:

**Karla Weaver et al.**

Serial No.: 10/608,660

Filed: June 27, 2003

For: PRESSURE ACTUATED VALVE  
WITH IMPROVED BIASING  
MEMBER

Group Art Unit: 3761

Examiner: Leslie R. Deak

**Board of Patent Appeals and  
Interferences**

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**REPLY BRIEF UNDER 37 C.F.R. § 41.41**

In response to the Examiner's Answer mailed on December 4, 2006 to the Appeal Brief filed August 31, 2006, and pursuant to 37 C.F.R. § 41.41, Appellants present this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1, 4-12, 15, 16 and 18-34 in the final Office Action dated March 7, 2006 as clarified in the Advisory Action dated July 3, 2006 and further clarified in the Examiner's Answer mailed December 4, 2006. The appealed claims are set forth in the attached Claims Appendix.

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Attorney Docket No.: 10123 - 00201

1. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 4-6, 8, 15 and 33 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,991,745 to Brown.
- II. Whether claims 29 and 31 are unpatentable under 35 U.S.C. § 103(a) as obvious over Brown.
- III. Whether claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over Brown in view of U.S. Patent No. 6,621,557 to Cushman et al. ("Cushman").
- IV. Whether claims 9-12, 16, 18, 22-27, 30, 32 and 34 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,810,789 to Powers in view of Brown.
- V. Whether claims 19-21 and 28 are unpatentable under 35 U.S.C. § 103(a) as obvious over Powers in view of Brown and further in view of Cushman.

2. Argument

I. The Rejection of Claims 1, 4-6, 8, 15 and 33 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 4,991,745 to Brown Should Be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, the Examiner maintains that Brown discloses "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. (See Examiner's Answer, pp. 7-9).

As discussed in the Appeal Brief dated August 31, 2006, Brown describes a disk-shaped valve including a slit surrounded by circular grooves 4 and a set of ribs 7 extending radially from a center area of the valve. (See Brown, col. 6, lines 1-14). The valve is integrally molded as a unitary element from a liquid silicone rubber. (Id. at col. 5, lines 42-50). The Examiner contends that the term "coupled" as recited in claim 1 may be read to include integral elements such as Brown's ribs as long as the elements are separate. (See Examiner's Answer, p. 8). The Appellants respectfully disagree with the Examiner's interpretation of the term "coupling." According to the Examiner's definition of this term, two elements need not be

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discrete in order to be coupled. Nevertheless, the Examiner concedes that the elements must be separate, even if formed integrally. In essence, this definition advances the concept of distinctness argued by the Appellants in the Appeal Brief. No aspect of the ribs is distinguishable from the rest of the valve. Brown discloses that the ribs are formed of the same material and with the same thickness as the rest of the valve. (See Brown, col. 6, lines 44-50). Thus, the ribs are extensions of the valve itself and are indistinguishable. Furthermore, it appears that the Examiner bases the distinction of the ribs solely on the purported functionality thereof, rather than any physical distinction between the ribs and the valve. Thus, the Appellants respectfully maintain that the ribs are not coupled to the valve.

The Examiner also maintains that Brown's disclosure of the ribs as selectively stiffening the valve shows biasing members. Appellants respectfully submit that the ribs do not possess any inherent stiffening characteristics and therefore cannot constitute biasing members. Rather, the ability of the ribs to stiffen arises from the extension of the ribs into the circular grooves. Brown attributes the stiffening to the "additional thickness of [the] ribs." (*Id.*). The ribs accommodate the grooves, functioning as points of attachment for the valve. Thus, the stiffening is a result of the configuration of the entire valve relative to the grooves and not a property of the ribs themselves. The "additional thickness" alone does not enable stiffening. The Examiner states that if Brown's valve were formed without the ribs, the valve would have a different opening pressure. However, this only shows that it is the interaction between the grooves and the valve itself which controls the opening of the valve. The addition of the ribs represents a controlling of this interaction through changing the shape of the valve. This is not equivalent to coupling a biasing member to a valve.

Based on the reasons discussed above, Appellants respectfully maintain that Brown neither discloses nor suggests "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. Therefore, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 102(b) of independent claim 1 and all the claims depending directly or indirectly therefrom (claims 4-6, 8, 15 and 33 ).

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II. The Rejection of Claims 29 and 31 Under 35 U.S.C.  
§ 103(a) as Obvious Over Brown Should Be Reversed

With reference to claims 29 and 31, the Examiner states that the threshold pressures recited therein are a result-effective variable, the range of which could be attained through optimization using routine skill in the art. (See Examiner's Answer, p. 9). However, the present invention is distinguished from Brown's valve by more than just a range of values. The threshold values are merely an indication of a fundamental difference between the types of applications to which the present invention and Brown's valve are directed. Brown provides no indication whatsoever that the disclosed valve is suitable for use in medical devices. Brown states that the size and shape of the valve orifice along with the thickness of the valve walls can be varied to change the threshold pressure. (See Brown, col. 6, line 64 - col. 7, line 10). However, it is unclear whether the valve could be successfully implemented in medical devices. Brown's valve is sized to work with fluid dispensing containers, which generally operate on a substantially different scale than that of medical devices. Furthermore, the types of pressures contemplated by Brown are those which are manually produced rather than anatomical in origin. Without any disclosure or suggestion from Brown, it cannot be said that the threshold pressures recited by claims 29 and 31 may be reached through mere experimentation using Brown's valve.

Based on these reasons and in addition to those reasons discussed with reference to claim 1, Appellants respectfully maintain that claims 29 and 31 are allowable and request that the Board overturn the rejection under 35 U.S.C. 103(a) of claims 29 and 31.

III. The Rejection of Claim 7 Under 35 U.S.C. § 103(a) as Obvious  
Over Brown in view of Cushman Should Be Reversed

The Examiner maintains that the wire spring taught by Cushman functions to bias the valve disc. (See Examiner's Answer, p. 9). In contrast to the Examiner's assertion that the combination of the spring and the insert serve to bias the valve, Appellants respectfully submit that neither of these components has any biasing effect whatsoever. The spring essentially acts as a spacer which occupies the space between the insert and skin sheet. The only purpose of the spring is to, via the taking up of space, prevent motion of the insert. Furthermore, even if the spring did produce a compressive biasing force against the insert, such a force would not be

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transferred to the valve. The insert comprises a rigid barrel that also does not have any biasing effect on the valve. The insert merely houses the valve and any closing ability of the valve is attributed not to the insert or the spring, but to the valve itself. Thus, it is respectfully maintained that neither Brown nor Cushman, either alone or in combination, disclose or suggest "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1.

The Examiner also contends that the recitation "for biasing the first and second flaps toward the closed position" relates to an intended use rather than a structural limitation. Appellants respectfully disagree. This recitation lends critical meaning to the term "biasing member" and explains the nature of the biasing member in terms of its function. Thus, the Examiner's interpretation of Cushman's spring as biasing the insert to a particular position is irrelevant. Moreover, such an interpretation produces the untenable conclusion that Cushman's spring is somehow equivalent to Brown's ribs when the alleged biasing ability of each is different from the other.

In addition, the Examiner combines the teachings of Brown and Cushman by asserting that it would be obvious to use a metal rib as a biasing means in Brown's valve. (See Examiner's Answer, pp. 9-10). However, claim 7 specifically recites that the biasing member is formed of a wire. The Examiner references the wire spring of Cushman, yet discards this teaching by transforming the wire spring into a metal rib. It is clearly impossible to form the ribs as wires. The ribs are individually located throughout the perimeter of Brown's valve and must accommodate the grooves, whereas Cushman's spring must circumscribe the entire insert. Thus, Brown's ribs are both functionally and structurally distinct from Cushman's spring.

Based on these reasons and in addition to those reasons discussed with reference to claim 1, Appellants respectfully maintain that claim 7 is allowable and request that the Board overturn the rejection under 35 U.S.C. 103(a) of claim 7.



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IV. The Rejection of Claims 9-12, 16, 18, 22-27, 30, 32 and 34 Under 35 U.S.C. § 103(a) as Obvious Over Powers in view of Brown Should Be Reversed

Appellants respectfully maintain that Powers does not cure the deficiencies of Brown and that neither Powers nor Brown, either alone or in combination, disclose or suggest "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. In addition, despite the Examiner's contention that Powers and Brown are combinable because both are directed toward flow control, Powers discloses a valve which has a substantially different structure than that of Brown's valve. Powers describes a radially flexing valve formed by cutting a slit into a catheter wall. The valve taught by Brown is formed as a disc and is not operable between inwardly and outwardly open positions. Therefore it would not be possible to combine the teachings of Powers and Brown.

Based on these reasons, the Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 103(a) of claims 9-12. Independent claim 16 recites limitations substantially similar to claim 1. Accordingly, the Appellants also respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 103(a) of claim 16 and all claims depending therefrom (claims 18, 22-27, 30, 32 and 34).

V. The Rejection of Claims 19-21 and 28 Under 35 U.S.C. § 103(a) as Obvious Over Powers in view of Brown and Further in view of Cushman Should Be Reversed

The Appellants respectfully maintain that neither Powers, nor Brown nor Cushman, either alone or in combination, teach or suggest "a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position," as recited in claim 16 and the Board should overturn the Examiner's rejection under 35 U.S.C. 103(a) of claim 19-21 and 28, which depend from claim 16.

Therefore, at least for these reasons and the reasons in the previously filed Appeal Brief, it is respectfully submitted that all of the presently pending claims are allowable. Appellants respectfully requests that the Board overturn the Examiner's rejection of these claims.

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3. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse all of the final rejections of the claims and indicate that claims 1, 4-12, 15, 16 and 18-34 are allowable.

Respectfully submitted,

Date: February 2, 2007

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**CLAIMS APPENDIX**

1. (Rejected) A valve for controlling material flow through a catheter, comprising:

a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen; and

a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position.

4. (Rejected) The valve according to claim 1, wherein the first slit is substantially linear.
5. (Rejected) The valve according to claim 4, wherein the first biasing member extends around the first slit.
6. (Rejected) The valve according to claim 5, wherein the first biasing member is substantially rectangular.
7. (Rejected) The valve according to claim 1, wherein the first biasing member is formed of a wire embedded within the first flexible member.
8. (Rejected) The valve according to claim 4, wherein the flexible member is formed substantially as a disc and where the first slit extends substantially parallel to a major axis of the disc.
9. (Rejected) The valve according to claim 1, further comprising:

a housing in which the first flexible member is mounted, the housing comprising

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first and second lumens, the first flexible member being mounted within the first lumen and a second flexible member formed as a sheet of polymeric material being mounted within the second lumen, the second flexible member including third and fourth flaps remaining in a closed position at all times when a fluid pressure exerted thereagainst is lower than a further threshold level, the third and fourth flaps moving into an open position in which material may flow past the second flexible member through the second lumen when the fluid pressure thereagainst is at least the further threshold pressure; and

a second biasing member coupled to the second flexible member for biasing the third and fourth flaps toward the closed position.

10. (Rejected) The valve according to claim 1, wherein the first and second flaps are separated by first and second substantially parallel slits.
11. (Rejected) The valve according to claim 9, wherein the housing is adapted to couple to a first external line to the first lumen for supplying blood to a dialysis machine and to couple the second lumen to a second external line for receiving blood from the dialysis machine.
12. (Rejected) The valve according to claim 9, wherein the housing is a unitary part of the catheter.
15. (Rejected) The valve according to claim 1, wherein the first flexible member is formed as a silicone disc.
16. (Rejected) A valve housing for a catheter comprising:

a first end permanently coupled to a patient line a distal end of which is to be implanted within a patient's body and a second end connectable to an external line;

a housing flow passage fluidly coupled to a flow passage of the patient line and selectively coupleable to a flow passage of the external line; and

a valve mounted within the housing flow passage to selectively restrict flow of

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materials therethrough, the valve being formed as a sheet of polymeric material and including:

first and second flaps separated from one another by a first slit in the sheet, the first and second flaps opening when a fluid pressure applied to the valve is at least a threshold pressure and remaining closed when the fluid pressure applied thereto is less than the threshold pressure; and

a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position.

18. (Rejected) The valve housing according to claim 16, wherein the first biasing member is embedded within the flexible sheet.
19. (Rejected) The valve housing according to claim 18, wherein the first biasing member is formed of at least one length of wire.
20. (Rejected) The valve housing according to claim 19, wherein the at least one length of wire extends around the first slit.
21. (Rejected) The valve housing according to claim 20, wherein the at least one length of wire comprises a plurality of unjoined wire segments.
22. (Rejected) The valve housing according to claim 18, further comprising a second biasing member, the first biasing member extending substantially parallel to the first slit on a first side thereof and the second biasing member extending substantially parallel to the first slit on a second side thereof opposite the first biasing member.
23. (Rejected) The valve housing according to claim 22, further comprising at least one third biasing member extending substantially perpendicular to the first slit and separated from an end of the first slit.
24. (Rejected) The valve housing according to claim 23, wherein the at least one third biasing

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member includes a pair of third biasing members extending adjacent to opposite ends of the first slit.

25. (Rejected) The valve housing according to claim 24, further comprising a pair of second slits extending substantially perpendicular to the first slit at opposite ends thereof to form an H-shaped arrangement of slits, wherein the third biasing members are radially outside the second slits with respect to the first slit.

26. (Rejected) The valve housing according to claim 20, further comprising a second slit extending substantially parallel to the first slit within the first biasing member.

27. (Rejected) The valve housing according to claim 16, further comprising a pair of second slits, each of the second slits extending away from a first end of the first slit at a predetermined angle and a pair of third slits, each of the third slits extending away from a second end of the first slit opposite the first end at a predetermined angle.

28. (Rejected) The valve housing according to claim 27, wherein the valve is formed as a sheet of flexible material and wherein the first biasing member comprises a wire embedded within the sheet of flexible material, the first biasing member extending around the first second and third slits.

29. (Rejected) The valve according to claim 1, wherein the threshold pressure is selected to be greater than pressures to which the valve will be subjected by anatomical influences.

30. (Rejected) The valve according to claim 16, wherein the threshold pressure is selected to be greater than pressures to which the valve will be subjected by anatomical influences.

31. (Rejected) The valve according to claim 1, wherein the threshold pressure is below a pressure at which anatomical structures connected to the device will be damaged.

32. (Rejected) The valve housing according to claim 16, wherein the threshold pressure is below a pressure at which anatomical structures connected to the device will be damaged.

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33. (Rejected) The valve according to claim 1, wherein the first and second flaps open along a first direction in response to pressure along the first direction and along a second direction in response to pressure along the second direction, the first and second directions oriented opposite to each other along a longitudinal axis of the catheter.

34. (Rejected) The valve according to claim 16, wherein the first and second flaps open along a first direction in response to pressure along the first direction and along a second direction in response to pressure along the second direction, the first and second directions oriented opposite to each other along a longitudinal axis of the catheter.

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**EVIDENCE APPENDIX**

No evidence has been submitted herewith or is relied upon in the present appeal.



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**RELATED PROCEEDINGS APPENDIX**

There are no related proceedings and/or decisions which relate to the present  
appeal.